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ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

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RISK ASSESSMENT DIVISION (RAD) REQUEST FOR TASK ORDER PROPOSAL (RFTOP) PROJECT TITLE:

Preparation of Occupational Release and Exposure Assessments for EPA's Existing Chemicals Programs

C. Performance Work Statement (PWS)

C1. Background and Purpose

Background

The Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) is responsible for work under several statutes including, principally, the Toxic Substances Control Act (TSCA), the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends TSCA, and the Pollution Prevention Act of 1990 (PPA). OPPT's mission is to assure that industrial chemicals are designed, manufactured, processed and used in ways that (i) maximize their benefits to society while minimizing adverse impacts on human health and the environment; (ii) encourage the replacement of older, more hazardous chemicals and technologies with new, safer alternatives; and (iii) work to harness the use of pollution prevention technologies, whenever feasible.

OPPT's Risk Assessment Division (RAD) is responsible for conducting risk evaluations of chemicals regulated under TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Among other things, the new TSCA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation under the conditions of use. The Contractor shall be familiar with the amended TSCA law to ensure that technical products abide by the scientific standards that EPA must meet when preparing technical products supporting OPPT's risk evaluations.

Under the amended TSCA, EPA is required to systematically prioritize existing chemicals for risk evaluation¹. The prioritization process is bound by a minimum/maximum statutory deadline (9 months minimum/12 months maximum) during which EPA must designate the chemical substance as either a High- or Low-Priority substance.

¹ https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation

Risk evaluation for a substance begins immediately upon a High-Priority designation². Within six months from the date of announcing that a chemical substance is subject to risk evaluation, EPA will issue a final scoping document that will include information about the chemical substance, the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations (PESS) the agency expects to consider in the risk evaluation. TSCA generally requires that a final risk evaluation be published no later than 3 to 3.5 years after identifying a chemical as being a High-Priority substance. EPA is in the process of prioritizing and additional 40 chemical substances.

The Contractor is expected to support EPA's prioritization efforts, the development of scoping documents and draft/final risk evaluations for High-Priority substances. Below is a short description of the contents of the scoping documents as well as draft/final risk evaluations:

- 1. Scoping Document³: During this stage, OPPT determines the exposure pathways, receptors and health endpoints that will be the focus of the risk evaluation for a particular substance or cluster under specific TSCA uses. Conceptual models, key assessment questions and the analysis plan document the conclusions of the problem formulation. Conceptual models are developed to capture the exposure pathways, receptor populations and effects that will be included in the human health and ecological risk evaluation. The key assessment questions are developed to drive the scope and analysis plan of the human health and ecological risk evaluation. Note, that not all data sources need to be reviewed in detail for purposes of the scoping documents. Scoping documents are required within 6 months of designating high-priority chemicals.
- 2. Draft Risk Evaluation and public comment: This step involves developing a risk evaluation document containing the technical contributions of multiple disciplines. The description here is specific to exposure assessment. All monitoring studies should be reviewed, relevant information extracted, and media-specific information incorporated into reporting tables. All modeling scenarios should be defined, estimated or measured model inputs defined, model choice documented, and model outputs (deterministic or probabilistic) documented. The combination of monitored and/or modeled estimates of media-specific concentration and dose should be aggregated, as appropriate, for defined receptor groups including potentially exposed and susceptible subpopulations (PESS), to the extent data are available.
- 3. **Final Risk Evaluation:** Should additional information become available through public comment, literature review, required testing, or other sources, EPA will update its draft risk evaluation to refine existing exposure scenarios, develop new scenarios, or combine scenarios for purposes of aggregate exposures for receptor groups in different ways.

Furthermore, the new TSCA legislation requires that EPA adhere to specific provisions regarding Scientific Standards, Weight of Scientific Evidence, and Availability of Information as articulated in Sections 2625 (h), (i), and (j) of TSCA, respectively⁴. To address these provisions, OPPT uses "fit-for-purpose" systematic reviews. The Contractor shall follow EPA guidance with respect to application of

² https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca/risk-evaluation

³ The amended TSCA uses the term "scoping document" which is equivalent to "problem formulation". Examples of problem formulation documents can be found at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/evaluation

⁴ http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim

systematic review in TSCA risk evaluations⁵. Below is a brief description of the steps in a fit-for-purpose systematic review:

- 1) Data Collection: OPPT intends to collect most of the data/information upfront to support development of scoping documents and chemical risk evaluations. Data will be collected under a defined set of literature search criteria and data sources for the different disciplines supporting the risk evaluation (chemistry, fate, engineering, exposure, human health hazard toxicology, ecotoxicology). The HERO database⁶ will be used as an overall repository for all identified data sources. HERO access will be provided to the Contractor supporting this task order. However, another contractor will take the lead for conducting the majority of the data collection activities.
- 2) **Data Evaluation:** During this phase, the collected data/information are critically appraised to determine their quality and utility. It can be subdivided further into the following steps:
 - a. Screening of literature to identify data/information that are potentially suitable and useful in the scoping document and risk evaluation. This review includes title review and abstract review. Search strategies and review criteria (inclusion/exclusion) will need to be documented, including using of tagging tools within HERO. Another contractor will be performing these steps.
 - b. Extraction, tabulation and development of study summaries which will assist in the evaluation of the reliability and relevance of studies. The Contractor for this task order may be asked to provide support for this step.
 - c. Evaluation of the reliability and relevance of studies to determine whether the information is of appropriate quality to be used in the assessment. For purposes of developing conceptual models and analysis plans in the scoping documents, chemical-specific, use-specific (from use dossiers), and discipline-specific data sources (from the Data Collection step) will be analyzed at a high-level to inform development of exposure scenarios that will be assessed during risk evaluation. This may include full-text review for a subset of the identified data sources. The Contractor for this task order may be asked to provide support for this step.
- 3) **Data Integration:** This is the step where all of the relevant data are combined and analyzed. OPPT uses a weight of evidence (WOE) approach when evaluating and synthesizing multiple evidence streams to support chemical risk evaluations. The Contractor for this task order may be asked to provide support for this step.
- 4) **Summary of Findings and Identification of Data Gaps:** OPPT will take risk management actions when unreasonable risks are identified throughout the risk evaluation process. Thus, it is critical that the findings of the systematic review are summarized in plain language, and any uncertainties and areas for further research are identified. The Contractor for this task order may be asked to provide support for this step.

⁵ https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations

⁶ Health and Environmental Research Online (HERO): https://hero.epa.gov/hero/

Purpose

The primary purpose of this task order is to support preparation of Occupational Release and Exposure Assessments for EPA's Existing Chemicals Programs. Relevant support items include but are not limited to the following:

- 1. Descriptions of processes and technologies for manufacturing, processing and using specific chemicals or categories of chemicals that serve specific functions;
- Occupational exposure assessments, including characterizations of the potential for occupational exposure, estimates of the number of workers potentially exposed and levels of inhalation and dermal exposure;
- 3. Environmental release assessments, including identification of sources of potential environmental release and estimates of the levels of release;
- 4. Potential pollution prevention and exposure reduction opportunities;
- 5. Effectiveness of personal protective equipment, engineering controls and waste treatment processes such as publicly owned treatment plants (POTW);
- 6. Development and application of occupational exposure and release mathematical models;
- 7. Other topics may include the following:
 - a. Risk assessment calculations
 - b. Sampling and chemical analysis plans or protocols for the collection of environmental release data
 - c. Environmental monitoring studies
 - d. Sampling and analytical chemistry methods for the collection of workplace exposure monitoring data

Under this task order, the Contractor will continue work on risk evaluations currently underway. The Contractor will also support prioritization efforts, the development of scoping documents and risk evaluations for the additional chemicals listed in Table 1. For these additional chemicals, the Contractor will initially support prioritization efforts, development of the scoping documents and then move to work supporting the analysis phase of the risk evaluation. However, additional work beyond this list of chemicals is anticipated, including technical support for risk management activities.

The Contractor will develop various technical products to support these activities such as, but not limited to occupational chemical release assessments and characterizations; exposure assessments and characterizations; briefing presentations, white papers; response to comments; generation of release and exposure model inputs and outputs; model maintenance, development, or refinement; database development; Quality Assurance and/or Quality Control of project plans and/or of work products; supplemental fit-for-purpose literature searches; develop and maintain Endnote libraries; identify and summarize monitoring data; additional related tasks that will be clarified as indicated in the PWS.

Table 1: This task order is expected to initially support preparation of Occupational Release and Exposure Assessments for these chemicals. However, additional work beyond this list is anticipated.

	Phase					
Chemical Name	Prioritization	Scoping Document	Draft Risk Evaluation	Final Risk Evaluation	Risk Management	
Trichloroethylene (TCE)	Ø	\square		×	×	
Methylene chloride (DCM)	Ø	\square		×	×	
N-Methylpyrrolidone (NMP)	Ø	\square		×	×	
1,4 Dioxane	Ø	\square		×	×	
Cyclic Aliphatic Bromide Cluster (HBCD)	Ø	\square		×	×	
1- Bromopropane (1-BP)	Ø			×	×	
Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f'] diisoquinoline-1,3,8,10(2H,9H)-tetrone)	Ø	Ø		×	×	
Carbon Tetrachloride	Ø			×	×	
Tetrachloroethylene (also known as perchloroethylene)	Ø	Ø		×	×	
Asbestos	☑			×	×	
20 additional EPA-initiated risk evaluations		×	×	×	×	
5 additional Manufacture-requested risk evaluations		×	×	×	×	
☐ = in-progress ☑ = complete ☒ = not started						

C2. Scope of Work

The purpose of this procurement is to provide time and materials support for the preparation of Occupational Release and Exposure Assessments for EPA's Existing Chemicals Programs. The Contractor shall supply the necessary resources required for the performance of this contract. The scientific quality of reviews, assessments, reports, model tools, statistical programs and software, and their timely preparation in accordance with negotiated schedules, are of paramount importance in the performance of this contract.

The Contractor shall have the necessary technical and scientific expertise, knowledge and experience to successfully perform all of the tasks identified below. In addition, the Contractor shall have a quality assurance/quality control program that maintains the quality of products, as well as an ongoing training program. This is intended to ensure that the contract staff produces quality products, and feedback from OPPT on needed improvements is communicated to the contractor's staff. The Contractor shall maintain and make available upon request complete documentation of QA/QC practices and procedures.

Performance of work under this contract shall be initiated by competitive task orders issued by the Contracting Officer (CO) and will encompass the tasks described in Section: C3. Tasks.

C3. Tasks

TASK 1: Project Management

The Contractor shall provide a Project Manager. The Contractor Project Manager shall report on all aspects of the objectives and progress of this contract to the designated EPA Contracting Officer (CO) and Contracting Officer Representative (COR) via email, through monthly reports. The Contractor Project Manager also plans, conducts and supervises Task Order (TO) projects, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. The Contractor Project Manager provides advice and counsel to other professionals. The Contractor Project Manager shall notify via email the relevant EPA COR/Alternate COR or TO COR of any significant difficulties in accomplishing the task listed in the TOs.

In cases where performance objectives and minimum Acceptable Quality Levels (AQLs) are not being met, the Contractor Project Manager will make every effort to immediately correct the problems to ensure customer satisfaction. If the problem persists, the Project Manager will submit a plan of corrective action to the TO COR and the Contract Level COR. The Contractor Project Manager shall ensure that the approved Quality Assurance (QA)/Quality Control (QC) process is followed to ensure the quality of its products.

The Contractor shall schedule a kick-off call with EPA to review overall goals of the project and details regarding implementation of the TO. Roles and responsibilities for completing the tasks below will be discussed. The kick-off call shall be scheduled within 3 working days of award at a mutually agreed upon time. During the kick-off call the Contractor and EPA will schedule monthly technical calls.

TASK 2: Reporting Requirements

The Contractor shall write and submit monthly progress reports to the EPA Contracting Officer Representative (COR). Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

Routine progress reports shall include a written monthly technical progress report (TPR) that includes the following in the case of each project that the Contractor is involved in during the month: (a) an overview of work accomplished since project inception to to-date (b) a description of work accomplished during the month, (c) a summary of QA/QC activities since project inception including a summary of corrective actions taken (d) a brief summary of anticipated work during the following month, (e) a summary and details of the level of effort (LOE) and costs incurred **for each task (where applicable for each task by chemical by labor category)** during the month and cumulatively, and (f) total remaining LOE and budget. This report shall also be issued to the Contract Level COR. Routine progress reports shall be delivered electronically; paper copies are not needed.

The Contractor shall notify the TO COR and CO when 75, 90, and 100% of approved hours have been expended. No work on the conduct of environmental data operations can begin until EPA approval of

the Quality Assurance Project Plan (QAPP) is obtained. Work not related to environmental data operations such as scoping how environmental data may be searched for or summarized once available including refinement of keywords, criteria, or report templates may begin prior to QAPP approval. See Section H (Invoice Preparation Instructions: SF 1035) for additional invoice reporting instructions.

Failure to submit monthly progress reports with the information required will result in the suspension of the invoice until such supporting documentation is provided. Any deviations from the project such as work schedules, impediments encountered, and budget require approval from the EPA COR. The EPA COR may also initiate verbal communications with the Contractor on an as needed basis to determine project status.

<u>Deliverable</u>: Monthly Progress Reports shall be submitted to the EPA COR within three (3) calendar days of invoice submission to EPA. Minimal level of effort required for this deliverable.

TASK 3: QAPP Requirements

Quality Assurance: The Quality Management Plan, the QAPP for Tasks 4 through 8. The Contractor shall adhere to its Quality Management Plan that is tailored for this contract.

This task order involves the use of existing data. Accordingly, EPA policy requires that an approved Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. The QAPP must be consistent with EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5⁷

- Within 10 business days after Task Order Award, the Contractor shall prepare and submit for EPA review a draft Quality Assurance Project Plan (QAPP) for Tasks 4 through 8.
- EPA will review the Contractor's draft QAPP and provide the Contractor with written approval or written comments.
- If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TO COR.
- Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TO COR that EPA has approved the contractor's QAPP.

All QA documentation, including the QAPP, prepared under this TO, shall be considered non-proprietary, and shall be made available to the public upon request.

⁷ https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf

Additional QA Documentation Required

In addition to the requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the Contractor under this task order must include a discussion of the QA/QC activities that were or will be performed to support the deliverable. The Contractor shall immediately notify the EPA TO COR of any QA problems encountered that may impact the performance of this task order, with recommendations for corrective action.

The Contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this task order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken. The Contractor may include this as a part of the contract-required monthly financial/technical progress report. The Contractor shall notify the EPA TO COR at any time during the task order if changes to the QAPP are warranted (e.g., due to organizational changes, revised technical approaches).

If, during the Period of Performance of this task order, the EPA TO COR determines revisions to the QAPP are necessary, the contractor shall submit a revised QAPP, including the revision summary, within 5 business days after receiving written technical direction to do so. EPA will review the draft revised QAPP and provide the Contractor with written approval or comments. The Contractor shall provide a revised QAPP, then a final QAPP that responds to EPA's written comments within 5 business days of receipt of EPA's comments on the draft QAPP.

Under no circumstances shall work involving environmental data be performed by the contractor until the contractor receives written notification from the EPA TO COR that EPA has approved the contractor's QAPP.

Since this task order involves the collection, evaluation, and use of environmental data by and for the Agency, the contractor shall implement a quality system that meets ANSI standard E4-2014 and prepare a quality assurance project plan (QAPP) following EPA guidelines. QAPP is due within 10 days of task order award.

TASK 4. Identification and Evaluation of Data Sources used for Scoping Documents

The Contractor shall document the approach taken to search for data sources used to support the development of scoping documents and risk evaluations for those chemicals listed in Table 1. The data sources will be used to develop a conceptual model and analysis plan, which document the conclusions of the scoping/problem formulation of each chemical listed in Table 1. Note that another contractor will be conducting the majority of literature searches. Fit for purpose supplemental literature searching may be initiated through technical direction to provide answers to specific questions.

EPA may identify additional candidate chemicals or categories during the period of performance of this task order, in addition to those listed in Table 1.

Subtask 4.1. Data Collection

In general, EPA anticipates that this task order will support focused data gathering activities. In that case, the Contractor shall perform data gathering activities in accordance with EPA's fit-for- purpose systematic review process. Specifically, the Contractor shall use the procedures and requirements presented in the background information document ("Background Information for QAPP Development") as guidance and shall adhere to the requirements of the QAPP and to any other relevant requirements issued by EPA. Before starting literature search, the Contractor shall develop a literature search and screening protocol, in collaboration with the EPA TO COR and EPA technical contacts, to describe the process(es) used to identify, and screen references. The literature searches and screening protocol shall include search terms geared to gather information on susceptible populations since the amended TSCA requires to incorporate susceptible populations in their risk evaluations. When performing the literature searches, the contractor shall communicate with the EPA TO COR and technical contacts regularly to ensure that searches are refined and focused.

The Contractor shall document the literature search strategy and findings in a document that will be provided to EPA as a deliverable. This document should include, as a minimum, the following:

- Keywords used and databases searched
- Number of references screened and selected, including criteria-based rationale for including and excluding records. Note review of title and abstract may be sufficient to screen some data sources, while full-text review may be needed for other data sources.
- Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)⁸ flow diagram
 that graphically illustrates the number of titles, abstracts, and full articles reviewed during the
 literature search process.

The Contractor shall prepare a reference library in the version of EndNote that will be specified by EPA and submit the library to EPA as a deliverable. The Contractor shall prepare all deliverables specified in (Subtask 4.1. Data Collection) subject to EPA's QA/QC requirements. The background information document includes guidance on EPA's quality assurance and control requirements (QA/QC), including guidance on EPA's fit-for-purpose systematic review process.

Deliverables: EndNote file is due within 3 weeks of receipt of technical direction from TO COR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TO COR.

Subtask 4.2. First Tier Data Evaluation and Synthesis

The Contractor shall review and categorize the references (data sources) that are selected as a result of (Subtask 4.1. Data Collection) and qualitatively, semi-qualitatively or quantitatively summarize the data and information that are contained in these references. The TO COR will issue chemical-specific technical direction to specify the level of data review and summarization that is sufficient (no more and no less) to enable development of conceptual model and analysis plan for the scoping documents (see TASK 5: Development Occupational Exposure and Environmental Release Characterizations for Scoping Documents).

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⁸ http://prisma-statement.org/

The Contractor shall evaluate the relevancy and quality of the data and information contained in the summaries prepared as a result of the technical direction mentioned above to ensure that all data utilized for the preparation of the Scoping Documents are of adequate quality. The Contractor shall document the evaluation of data relevancy and quality of the summarized data and provide a report to EPA as deliverable; The Background Document for Developing QAPP contains guidance for accomplishing these requirements.

Deliverables: End note file and accompanying report (Microsoft Word or Excel) documenting criteria and screen to identify data sources used is due within 3 weeks of receipt of technical direction from TO COR. The report will be used to integrate into HERO this part of the systematic review. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TO COR.

Individual interim products shall be delivered to the TO COR within 2 weeks of receipt of written technical direction from the TO COR, and final exposure assessments shall be delivered to the TO COR within 1 week after comments received on interim assessments from EPA.

TASK 5: Development Occupational Exposure and Environmental Release Characterizations for Scoping Documents

The contractor shall develop occupational exposure and environmental release characterizations for the chemicals identified in Table 1 (although additional chemicals may be added during the period of performance of this task order). The contractor shall analyze and integrate the data/information into a sound exposure and environmental release characterization, including qualitative, semi-quantitative, and/or quantitative analysis of the available data sources. Data and information will include monitoring data and modeling approaches, as pertinent. Exposure characterizations may include narratives or graphics that support development of conceptual models, description of analysis plan, or overall approaches to complete an exposure assessment.

Refer to (Subtask 4.2. First Tier Data Evaluation and Synthesis) for EPA's QA/QC requirements that pertain to any data or information that is incorporated into the Occupational Exposure and Environmental Release Characterizations.

Deliverables: Individual interim products shall be delivered to the TO COR within 2 weeks of receipt of written technical direction from the TO COR, and final exposure characterizations shall be delivered to the TO COR within 1 week after comments received on interim assessments from EPA.

TASK 6: Development of Occupational Exposure and Environmental Release Assessments for Risk Evaluations

Subtask 6.1 Occupational Exposure and Environmental Release Assessment Support

The contractor shall develop occupational exposure and / or environmental release assessments for chemicals or categories identified by EPA. The assessments incorporate and interpret information on chemistry, and uses as produced by other disciplines. These assessments include update to literature search described in (TASK 4. Identification and Evaluation of Data Sources used for Scoping Documents), monitoring data compilation and summarization, derivation of model inputs and outputs, uncertainty and sensitivity analysis. The contractor shall evaluate, integrate, and summarize the data sources identified through systematic review with QA/QC of all data delivered to EPA for incorporation into the risk evaluation.

Deliverable- Individual interim products shall be delivered to the TO COR within 2 months of receipt of written technical direction from the TO COR, and final exposure assessments shall be delivered to the TO COR within 1 month after comments received on interim assessments from EPA.

Subtask 6.2. Data Collection

There may be circumstances that a limited literature search may be needed due to new literature published since the cut-off date for the literature search done as part of (Subtask 4.2. First Tier Data Evaluation and Synthesis), or information received from the public during the public comment period. In that case, the contractor shall consult with the EPA TO COR on the nature and extent of the data gathering activities supporting the risk assessment. Supplemental literature searches will be conducted according to the strategy specified in (Subtask 4.1. Data Collection). The contractor shall update the report documenting the literature search strategy and findings and EndNote library to reflect new literature identified and considered for the exposure assessment.

Deliverables: Contractor deliverables for updated endnote library shall be delivered to the TO COR within 3 weeks of receipt of technical direction from EPA TO COR.

Subtask 6.3. Data Evaluation and Synthesis

The Contractor will build on the data evaluation and synthesis conducted during (Subtask 4.2. First Tier Data Evaluation and Synthesis). Since EPA must be transparent on the data considered and used for the risk assessment, the Contractor shall extract information from identified literature in (Subtask 4.2. First Tier Data Evaluation and Synthesis) and (Subtask 6.2. Data Collection) using a template table provided by EPA. The Contractor may modify template table in consultation with the EPA TO COR. The Contractor will extract information into template table and provide it to EPA as deliverable. The Contractor shall perform a quality assurance check for the data tables prior to delivering them to EPA. Quality assurance checks shall include, but not limited to comparing table entries to information from the original publication and checking conversions as appropriate (e.g., ppm to mg/m3). The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. The contractor shall update the report documenting the screening process for evaluating relevancy and quality when new literature is considered for the risk assessment. The relevancy and data

quality screening process will follow the criteria outlined in the background information document and provide report to EPA as deliverable.

Deliverables: Contractor deliverables for updated list of data sources identified for inclusion in assessment shall be delivered to the TO COR within 3 weeks of receipt of technical direction from EPA TO COR.

TASK 7: Development of Other Technical Analyses or Documents Related to Prioritization, Scoping, Risk Evaluation, and Risk Management Activities

As requested by the EPA TO COR through technical direction, the Contractor shall prepare other technical analyses or documents related to prioritization, scoping, risk evaluation, and risk management activities.

Examples include other analyses or documents related to scoping documents, risk evaluations, peer review and public comments, and to worker protection and release mitigation.

Deliverables: Within 2-3 weeks for draft, within 1 week for final

TASK 8: Providing Support to Risk Management Related Activities

When requested by the EPA TO COR through Technical Direction, the Contractor shall prepare meeting materials related to the findings of the research and analyses conducted in the following tasks and present these materials during public meetings (e.g., workshops): TASK 5: Development Occupational Exposure and Environmental Release Characterizations for Scoping Documents; TASK 6: Development of Occupational Exposure and Environmental Release Assessments for Risk Evaluations; and TASK 7: Development of Other Technical Documents Related to the Scoping, Risk Evaluation, and Risk Management Activities.

When requested by the EPA's TO COR through technical direction, the Contractor shall facilitate public meetings about occupational exposure to or releases of existing chemicals or support these meetings by taking notes and preparing reports.

Deliverables: Within 2-3 weeks for draft, within 1 week for final

TASK 9: Prioritization Support

The purpose of prioritization is to designate a chemical substance as either High-Priority for further risk evaluation, or Low-Priority for which risk evaluation is not warranted at the time. By December 22, 2019, EPA must have designated at least 20 chemical substances as High-Priority and 20 chemical substances as Low-Priority. TSCA further requires that upon completion of a risk evaluation (other than those requested by a manufacturer), EPA must designate at least one additional High-Priority chemical to take its place, thus ensuring that the EPA's risk evaluation queue always remains full. Prioritization is

a priority-setting step. Tasks to support prioritization efforts may include but are not limited to (i) identifying uses for a chemical, (ii) identifying the relevant industries manufacturing, processing, or using a chemical, (iii) preparing prioritization documents, (iv) searching for readily available information for a chemical (e.g., OSHA PEL, NIOSH studies, assessments by the U.S. or other countries). Additional information about EPA's prioritization of existing chemicals for risk evaluations⁹ and EPA's current working approach for identifying potential candidate chemicals for prioritization ¹⁰ are also available.

Deliverables: Within 2-3 weeks for draft, within 1 week for final

C4. Reporting Requirements and Deliverables

As described in (TASK 2: Reporting Requirements) and in the invoice instructions, the Contractor shall provide a monthly report CO, COR and TO COR which identifies project staff and all activities and milestones associated with the task order assignments planned and in progress. The monthly report in progress tasks shall be included in the monthly reports which will be referenced when the Voucher Validation review is performed monthly at the end of each billing cycle.

As per the task order or request for a proposal, the Contractor shall provide the Agency with a proposal within the timeframe specified for this task order. The EPA CO, CORs, or panel members will review the proposal and provide the Contractor with an approval or disapproval, and revision (if necessary) in writing. The timelines involved, will proceed as stipulated in the request for a proposal or Contract

The Contractor shall prepare a Quality Assurance Project Plan for this Task Order. <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5).</u>

For most deliverables, the EPA COR will assign a tentative due dates and instructions when work is routed to the Contractor. If within three business days, the Contractor expresses no concern regarding the due date; the date shall be deemed settled by tacit agreement.

SPECIFIC SCHEDULE OF DELIVERABLES:

Tasks	Deliverables	Schedule
Task 1	Project Management	None
Task 2	Monthly progress reports	Monthly reports
Task 3	QAPP and monthly progress reports	QAPP: Within 10 business days after award of task order

⁹ https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation

 $^{^{10} \}underline{\text{https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/identifying-existing-chemicals-prioritization-under-tsca}$

Tasks	Deliverables	Schedule
Task 4	Supplemental Data Collection and Summarization for the Preparation of Scoping Documents	 4.1 Final products shall be submitted within 3 weeks of receipt of technical direction from TO COR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TO COR. 4.2. Final products shall be submitted within 3 weeks of receipt of technical direction from TO COR. Depending on the number of data sources identified and the number of concurrent searches this timeframe may extended no more than 2 weeks based on feedback from EPA TO COR.
Task 5	Occupational Exposure and Release Characterizations	Within 2 weeks for draft, within 1 week for final.
Task 6	Occupational Exposure and Release Assessments	 6.1 Within 2 months for draft, within 1 month for final. 6.2 Within 3 weeks of receipt of technical direction from EPA TO COR. 6.3 Within 3 weeks of receipt of technical direction from EPA TO COR.
Task 7, 8, and 9	Reports, Analyses, Presentations, etc.	Within 2-3 weeks for draft, within 1 week for final.

C5. Acceptable Quality Level for Tasks

See Attachment: Quality Assurance Surveillance Plan

Performance Criteria Analysis – TASKS					
Performance Indicator	Standard	Acceptable Quality Level (AQL)			
Timely submission of report	Reports submitted within time frame pre- negotiated with task order COR	95%			
Free of substantive technical, guideline, or format errors	Reports submitted with zero substantive errors including but not limited to discrepancies, omissions, inaccuracies, and/or inappropriate data evaluation	95%			

C6. Method of surveillance

Final deliverables prepared by the Contractor undergo a secondary review process in OPPT. Each report has a designated EPA reviewer. The EPA reviewer conducts a review of the Contractor's deliverable. The EPA reviewer will provide feedback to the TO COR to send back to the contractor should revisions be needed. The TO CORs will compare agency due dates or approved revised due dates to completed date of reports, quarterly and calculate the percentage of late reports.

C7. Period of Performance

The period of performance of this task order is:

- Base: 12 months from date of award
- Option 1: 12 months from date option exercised

C8. Task Order Type

Time and Materials

D. Inspection and Acceptance

D1. Quality Assurance Project Plan

The Contractor shall submit the following quality system documentation to the CO at the time frames identified below:

	Documentation	Specifications	Due
Х	Quality Assurance Project Plan for the Task Order	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/11]	Task Order proposal due date

This documentation can be found on the following EPA website – https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans

This documentation will be prepared in accordance with the specifications identified above or equivalent specifications defined by EPA.

The Government will review and return the quality documentation, with comments, and indicating approval or disapproval. If necessary, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The contractor shall not commence work involving environmental data generation or use until the Government has approved the quality documentation.

E. TASK ORDER ADMINISTRATION

E1. Contract Administration Representatives

Contracting Officer: Genine McElroy, McElroy. Genine@epa.gov

Contract Level Contracting Officer's Representative: Tyrone Thomas, Thomas.Tyrone@epa.gov

Task Order Contracting Officer's Representative: Rehan Choudhary, Choudhary.Rehan@epa.gov

Alternate Task Order Contracting Officer's Representative: Joseph Avcin, Avcin, Joe@epa.gov

F. Invoicing

Invoices shall be submitted electronically to: US EPA FINANCE OFFICE AT <u>DDC-KINVOICES@EPA.GOV.</u> Copy the CO, Contract COR and TO COR on the submission.

For format and guidance refer to: http://www2.epa.gov/financial/contracts#Contract invoices

The customer service contact information for the finance office is contractpaymentinfo@epa.gov and 919-541-1148.

G. TASK ORDER CLAUSES

G1.FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)

- (a) The Government may extend the term of this contract by written notice to the contractor within 5 calendar days before the expiration of this contract; provided that the Government gives the contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 months.

LOCAL CLAUSE - EPA-B-32-103A - LIMITATION OF GOVERNMENT'S OBLIGATION

a) Severable	serv	vices may	be inc	rementally funded.	Non-severable	services shall n	ot be ind	crementally	funded. Co	ntract
ine items	_1	through	2	_are severable and	may be increm	entally funded.	. For the	ese items, th	e sum of	
\$490,500.00	of th	e total pr	rice is p	resently available f	or payment and	d allotted to thi	s contra	ct.		

- (b) For items identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those items for the Government's convenience, approximates the total amount currently allotted for those items to the contract. The Contractor shall not continue work on those items beyond that point. Subject to the clause entitled, "Termination for Convenience of the Government," the Government will not be obligated, under any circumstances, to reimburse the Contractor in excess of the amount payable by the Government in the event of the termination of applicable contract line items for convenience including costs, profit, and estimated termination costs for those line items.
- (c) Notwithstanding the dates specified in the allotment schedule in paragraph (h) of this clause, the Contractor will notify the Contracting Officer, in writing, at least 5 days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85% of the total amount currently allotted to the contract for performance of the applicable items. The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of the applicable line items up to the next scheduled date for the allotment of funds identified in paragraph (a) of this clause, or to a substitute date as determined by the Government pursuant to paragraph (d) of this clause. If, after such notification, additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause entitled "Termination for Convenience of the Government."
- (d) The parties contemplate that, subject to the availability of appropriations, the Government may allot additional funds for continued performance of the contract line items identified in paragraph (a) of this clause and will determine the estimated period of contract performance which will be covered by the funds. If additional funds are allotted, the Contracting Officer will notify the Contractor in writing. The Contractor shall not resume performance of the contract line items identified in paragraph (a) until the written notice is received. The provisions of paragraphs (b) through (d) of this clause will apply in like manner to the additional allotted funds and to the new estimated period of contract performance. The contract will be modified accordingly.
- (e) The Government may, at any time prior to termination, allot additional funds for the performance of the contract line items identified in paragraph (a) of this clause.
- (f) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "Default". The provisions of this clause are limited to the work and allotment of funds for the contract line items set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded.
- (g) Nothing in this clause affects the right of the Government to otherwise terminate this contract pursuant to the contract clause entitled "Termination for Convenience of the Government".
- (h) The parties contemplate that the Government may obligate funds to this contract in accordance with the following schedule:

RECAPITULATION:

	PRIOR AMOUNT	THIS MOD.	NEW AMOUNT
BASE PERIOD			
Total Maximum Amount:	\$0.00	\$0.00	\$2,465,287.85
Funded Amount:	\$0.00	\$0.00	\$ 490,500.00

(End of clause)

G2.EPAAR 1552.237-72 Key personnel. (APR 1984)

(a) The contractor shall assign to this contract the following key personnel:

1. Project Manager:

The contractor shall identify a Project Manager to serve as USEPA's primary point-of-contact and to provide supervision and guidance for all contractor personnel assigned to the task order. The Project Manager is ultimately responsible for the quality and efficiency of the support effort, to include both technical issues and business processes. The Project Manager shall have knowledge in the technical areas described in the Task Order. The Project Manager shall assign tasks to contractor personnel, supervise on-going technical efforts, and manage overall task order performance. The Project Manager plans, conducts and supervises projects of major significance, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. Schedules work to meet completion deadlines. The Project Manager shall possess demonstrated excellent written and oral communications skills.

The Project Manager shall have experience in managing projects of similar size and scope as demonstrated by appropriate combination of education and experience.

2. Quality Assurance Manager

The Quality Assurance (QA) Manager must have experience in exposure assessment with the ability to critically evaluate the type of data described in the task order. The QA Manager shall have advanced knowledge and the ability to originate and apply new and unique methods and procedures. Provide technical advice and counsel to other professionals with special emphasis on procedures for execution of systematic review. Generally, operates with a wide latitude for non-reviewed actions or decisions. Schedules work to meet completion deadlines. Directs assistance, reviews progress and evaluates results; makes change in methods where necessary.

The QA Manager shall have experience in quality management, implementation of quality management plan, and ensuring quality of projects of similar size and scope as demonstrated by appropriate combination of education and experience.

(End of clause)

H. TSCA Scoping Document and Risk Evaluation Examples (Templates)

Caveats: These are examples rather than templates. Scoping documents were previously called "problem formulation and initial assessment" documents. The conceptual model and the analysis plan are the main products of the scoping process. The risk evaluations completed to-date have covered targeted uses. Risk evaluations under the new TSCA will require assessment of aggregate exposures to all exposed population groups including potentially exposed and susceptible subpopulations for all conditions of use, to the extent data are available to do so.

More information can be found at:

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten

I. Invoice Preparation Instructions: SF 1035

The information which a contractor is required to submit in its Standard Form 1035 is set forth as follows:

- (1) U.S. Department, Bureau, or Establishment insert the name and address of the servicing finance office.
- (2) Voucher Number insert the voucher number as shown on the Standard Form 1034.
- (3) Schedule Number leave blank.
- (4) Sheet Number insert the sheet number if more than one sheet is used in numerical sequence. Use as many sheets as necessary to show the information required.
- (5) Number and Date of Order insert payee's name and address as in the Standard Form 1034.
- (6) Articles or Services insert the contract number as in the Standard Form 1034.
- (7) Amount insert the latest estimated cost, fee (fixed, base, or award, as applicable), total contract value, and amount and type of fee payable (as applicable).
- (8) A summary of claimed current and cumulative costs and fee by major cost element. Include the rate(s) at which indirect costs are claimed and indicate the base of each by identifying the line of costs to which each is applied. The rates invoiced should be as specified in the contract or by a rate agreement negotiated by EPA's Cost Policy and Rate Negotiation Branch.
- (9) The fee shall be determined in accordance with instructions appearing in the contract.

<u>NOTE:</u> Amounts claimed on vouchers must be based on records maintained by the contractor to show by major cost element the amounts claimed for reimbursement for each applicable contract. The records must be maintained based on the contractor's fiscal year and should include reconciliations of any differences between the costs incurred per books and amounts claimed for reimbursement. A memorandum record reconciling the total indirect cost(s) claimed should also be maintained.

LIST OF ATTACHMENTS

ATTACHMENT 1: BACKGROUND INFORMATION FOR QAPP DEVELOPMENT

ATTACHMENT 2: QUALITY ASSURANCE SURVEILLANCE PLAN

J. INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

J1. EPA-L-15-102 TECHNICAL QUESTIONS

Offerors must submit all technical questions concerning this solicitation electronically through Fed Connect. In order to submit questions, offerors must register in Fed Connect at www.fedconnect.net, see main page for registration instructions. For assistance in registering or for other Fed Connect technical questions please call the Fed Connect Help Desk at (800) 899-6665 or email at support@fedconnect.net. Only those technical questions posted through Fed Connect will be accepted. EPA must receive technical questions no later than **7 calendar days** after the issuance date of this solicitation. EPA will utilize Fed Connect to issue amendments to the solicitation (e.g., to answer technical questions which may affect proposal submittal). EPA will not reference the source of the questions.

J2. Protests

No protest under FAR 33.1 is authorized, except for (1) a protest on the grounds that the order increases the scope, period, or maximum value of the contract, or (2) protests in excess of \$10 million may only be filed with the Government Accountability Office (GAO) pursuant to FAR 33.104. Refer to FAR 16.50.5

J3. EPA-L-36-101 RFTOP Proposal Instructions

- (a) Proposal Instructions
- (1) The offeror's response is to be submitted in two sections. Separate the technical proposal from the price proposal.

Responses are subject to the following requirements and limitations as set forth in this RFTOP:

SECTION	TITLE	PAGE LIMIT
I	Technical Proposal	25
Ш	Price Proposal	No Limit

(b) Section Specific Instructions

(1) Technical proposal instructions -

- (1) The technical proposal shall be complete and demonstrate an understanding of the work to be provided and the contractor's ability to perform the work in accordance with PWS. The technical proposal shall address all of the technical evaluation criteria presented in this section.
- (2) Each section of the proposal shall be titled.
- (3) Subcontractors

Each offeror shall list in a table format the name and addresses of all subcontractors who will perform work or labor or render services to the offeror for compensation in an amount in excess of one percent of the offeror's total price. Each offeror shall show on the table the portion of the work to be done by each subcontractor. This table shall be included with the technical proposal. The table shall include: (a) the name and location of the subcontractor, (b) a short description of the work the subcontractor will be designated to perform or deliver, (c) the portion in percent of the work the subcontractor will be designated to perform or deliver.

Technical Evaluation Factors

(a) FACTOR: TECHNICAL APPROACH

The offeror shall describe its technical approach, ability, and understanding of each task area in the task order PWS. In addition, the offeror shall provide information to demonstrate its knowledge and experience with regard to understanding of the regulatory requirements relating to the task.

(b) Past performance information shall be submitted with the business proposal. Offerors shall submit a list of up to three task orders of similar work completed, or currently in process, within the last 3 years. Include the following information for each task order listed:

(i) Name of contracting activity.
(ii) Task Order number
(iii) Task Order title.
(iv) Task Order type.
(v) Brief description of the task order and relevance to this requirement.
(vi) Total task order value.
(vii) Period of performance.
(viii) Contracting officer, telephone number, and E-mail address (if available).
(iv) Contracting Officer's Representative, telephone number, and E-mail address (if available).
(x) Administrative Contracting officer, if different from (h) above, telephone number, and E-mail address (if available).
(2) Business Proposal Instructions –
(a) Offerors shall break down the price by hours, tasks, labor categories and ODC's. Price analysis will be performed. Offerors must use the rates in the base contract or discounted rates.
Offers should provide sufficient detail to demonstrate the reasonableness of proposed costs. The burden of proof for credibility of proposed costs/prices rests with the offeror.

K. EVALUATION FACTORS FOR AWARD

K1. Basis for Award

The task order award will be based on a "best value with tradeoffs" analysis for this task order where technical is significantly more important than price.

ATTACHMENT 1: BACKGROUND INFORMATION FOR QAPP DEVELOPMENT

This document comprises guidance on EPA's quality assurance and quality control (QA/QC) requirements, including guidance on EPA's fit-for-purpose systematic review process. The specific data sources, search strategy, and criteria used for evaluation during systematic review may vary by the needs of each chemical assessment.

1. Data Needs, Sources, and Quality Criteria

This section discusses the data needed to achieve the objectives of the projects tasked under the Task Order, how the contractor will search for sources of these data, and the data quality criteria for these data.

1.1 Data Needs

The main data needs associated with typical project objectives are summarized in Table A1. the contractor will collect data to satisfy these data needs as appropriate, taking into consideration the project-specific objectives and scope. Alternatively, EPA may specify the data needs.

Data needs for assessments using mathematical models include the data inputs of a model. If the Contractor develops a mathematical model, data needs may also include the data needed to develop the model. The Contractor will report mathematical modeling data needs when seeking EPA's approval of model use or development

The Contractor may use surrogate data to satisfy a data need for which data are unavailable. Surrogate data are data for a surrogate property (e.g., a physical property, concentration, or process) or material (e.g., a specific chemical or combination of chemicals) that the Contractor determines is similar to the property or material of the required data input. For example, the Contractor may require data for a chemical in industry X. The Contractor may then find that data are not available for the chemical in industry X. However, data are available for the same chemical in industry Y. The Contractor uses professional judgment to determine that for the desired property, industry Y is similar to industry X. Therefore, the Contractor decides to use the data available for industry Y as surrogate data for industry X. This example demonstrates how the Contractor may use surrogate data under this Task Order. The Contractor will evaluate the applicability of surrogate data based on factors including, but not limited to, the following: physical properties, industry size, chemicals used, industrial processes, worker activities, levels of engineering controls, and personal protective equipment used. The Contractor will document any surrogate data and explain the rationale for their use.

If a project's objective is assessment of a grouping, or cluster, of similar chemicals (such as chemicals of similar molecular structure or chemicals that provide the same functional use, such as flame retardants), EPA may identify a single chemical of the cluster to serve as an index chemical. An index chemical may serve as a surrogate chemical for the other chemicals of the cluster if available data for other chemicals are limited.

Table A-1. Data Needs Associated with Typical Project Objectives

Objective Determined during Scoping	Data Need Type
All Objectives (including both Occupational Exposure and Environmental Releases)	 Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations.
Occupational Exposures	 Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. Greater exposure groups (likely based on use/task of job), as well as potential exposures to women of childbearing age and pregnant women. Potential routes of exposure (e.g., inhalation, dermal). Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage ofinterest). For solids, bulk and dust particle size characterization data. Dermal exposure data.

	 Data needs associated with mathematical modeling (will be determined on a case-by-case basis). Exposure duration. Exposure frequency. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. Personal protective equipment (PPE) types employed by the industries within scope. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions Description of sources of potential environmental releases, including
Environmental Releases	cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. 21. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (air, water, land) and treatment and disposal methods (POTW, incineration, landfill), including: 22. Releases per site and aggregated over all sites; 23. Annual release rates; 24. Daily release rates; 25. Release or emission factors; and 26. Number of release days per year. 27. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). 28. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions.

1.2 Data Sources

This section provides a discussion of the data sources that the Contractor will use to collect data to satisfy the data needs for a project. In general, there are two types of data: direct measurements and non-direct measurements.

Direct measurements are made by direct observation, typically via surveys or sampling programs. These surveys or sampling programs are designed to collect data to satisfy the data needs of a specific project because the data do not exist prior to their collection by direct measurement. the Contractor does not anticipate making direct measurements under this Task Order.

Non-direct measurements are data or information that the Contractor obtains by means other than direct observations, and these means include literature review and interviews of subject matter experts. These data are not newly generated under this Task Order. EPA QA/R-5, element B9, provides the

following examples of typical sources of non-direct measurement data: computer databases, programs, literature files, and historical databases (EPA, 2001). Under this Task Order, the Contractor may obtain non-direct measured data from the following data source types:

- Existing data sources, which include:
 - Journal articles
 - Published reports
 - Books
 - Government databases
 - Industry publications
- Primary data sources, which include:
 - Conducting interviews of subject matter experts

1.2.1 Sources of Existing Data

The Contractor performs a literature search to identify sources of existing data. The steps for performing a literature search are described in the following subsections.

1.2.1.1 Development of Keywords

The Contractor will develop a list of keywords or phrases that are pertinent to the objectives of the project. Keywords will be general enough to ensure information that is applicable to the chemical is identified, but specific enough to exclude most irrelevant information. Examples of keywords used to gather information for a chemical exposure assessment include:

- "1-bromopropane exposure"
- "1-bromopropane release"
- "1-bromopropane degreasing"
- "1-bromopropane spray adhesive"

Keywords should incorporate wildcards (*), as appropriate. For example, if "1-bromopropane degreasing" were identified as a keyword, then it would be feasible to also search for "1-bromopropane degreaser" and "1-bromopropane degreasers." Instead of listing these permutations individually, the keyword, "1-bromopropane degreas*" could be specified. Additionally, when searching using chemical names, chemical synonyms should be identified and included in the search. For example, a synonym of "1-bromopropane" is "n-propyl bromide." Therefore, all keyword searches performed for "1-bromopropane" should be repeated using "n-propyl bromide."

1.2.1.2 Search of Standard Engineering Sources

A list of standard engineering sources and the instructions for searching these standard sources are included in Appendix B. the Contractor will search these sources for all relevant information on the chemical of interest. The Contractor will use the keywords developed as described in Section 4.2.1.1 where applicable. Not all keywords apply to all standard engineering sources. For example, only the CAS number is needed to search TRI.

1.2.1.3 Open Literature Search

The Contractor may perform an open literature search using the keywords that are developed as described in Section 1.2.1.1. To conduct an open literature search, the Contractor uses Internet search engines to search for existing data sources. These Internet search engines include:

- Google: https://www.google.com/
- Google Scholar: https://scholar.google.com/
- The National Library of Medicine's PubMed: http://www.ncbi.nlm.nih.gov/pubmed

The Contractor will attempt to obtain original references cited for data or information in the reviewed sources. For example, if the Contractor identifies a literature source that cites data from a journal article, the Contractor will attempt to obtain the original journal article that the literature source cited.

As part of the open literature search, the Contractor will search for industry-specific publications and websites. For each industry that is relevant to the chemical of interest, there is usually at least one key trade association website, which may have available information. Some recent examples of trade association websites include:

- Silicones Environmental, Health, and Safety Center (SEHSC) of the American Chemistry Council (ACC) http://sehsc.americanchemistry.com/;
- International Fragrance Association North America (IFRANA) http://www.ifrana.org/.

In addition to trade associations, industries may have other types of industry-specific websites, such as industry-specific magazines. The following steps may be performed in this part of the literature search:

<u>Step 1: Identify Trade Associations and Publications and Books</u>: These sources are usually identified using an Internet search engine (e.g., Google) and the keywords. Note that additional keywords, such as "trade association", should also be entered into the search engine to help identify useful sources.

Step 2: Review all Web Pages, Publications, and Books: The Contractor will conduct a thorough review of all information available from these trade association websites because of the direct relevance of these sources. Review will include clicking through all of the links on the site and reviewing the information for the data listed in Table A1.

1.2.2 Sources of Primary Data

Only if directed to do so by EPA, the Contractor may collect non-direct measurements using primary data sources such as interviews of subject matter experts. The Contractor may conduct these interviews by telephone or email correspondence. Subject matter experts can include personnel employed in the following:

- Federal agencies, such as the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and EPA regional offices.
- State agencies, such as state departments of environmental protection.
- Universities, including state-university partnerships, such as the Toxics Use Reduction Institute (TURI) and the New York State Pollution Prevention Institute (NYSP2I).
- Consulting firms.
- Industry trade associations.

The purpose of these interviews is to collect anecdotal information, receive technical insights, or receive additional existing data sources (such as publications of which the subject matter expert is in possession) from the subject matter experts. Prior to contacting any individuals, the Contractor will prepare a subject matter expert contact plan, which will include the identity of individuals the Contractor will contact, the rationale for their inclusion in the plan, and the list of questions the Contractor will ask them. This contact plan will also include a discussion of whether or not an information collection request (ICR) is required in accordance with the Paperwork Reduction Act. If an ICR is required, the Contractor will support EPA in the preparation of an ICR package to be submitted for approval by the Office of Management and Budget (OMB). the Contractor will append the subject matter expert contact plan to this QAPP and submit the revised QAPP for EPA review and approval.

These interviews of subject matter experts are not surveys or polls, which are forms of direct measurements. Surveys or polls require that a statistical subset of the population, or the entire population, be sampled. the Contractor's contact plan will not plan for a survey of a statistical subset or an entire population. Rather, the Contractor will be soliciting select subject matter experts for their input on highly technical matters.

1.2.3 Direct Measurements

The Contractor does not anticipate making direct measurements under this Task Order. However, if EPA directs the Contractor to make direct measurements, the Contractor will discuss with the EPA Task Manager or the EPA WA COR a path forward for the development of a direct measurement plan. the Contractor anticipates that, if direct measurements are needed, we would make such measurements through the use of surveys. At the direction of EPA, the Contractor will develop a plan for making direct measurements and will modify this QAPP to describe data quality objectives, direct measurement methods (e.g., surveys), and other aspects of the direct measurement process to ensure the quality of the data. If a survey is the direct measurement method selected, the Contractor will also support EPA in the preparation of an ICR package for approval by OMB, if appropriate.

1.3 Data Quality Criteria and Acceptance Specifications

This section describes the measures and descriptions of quality that the Contractor will use to accomplish the following:

- 1. Identify data collected by the Contractor that are fit for purpose. In this Task Order, "fit for purpose" means that data meet the quality acceptance specifications.
- 2. Evaluate the quality of assessments or other technical reports prepared by organizations other than the Contractor (e.g., chemical manufacturers, trade associations).

1.3.1 Criteria for Evaluating the Quality of Data Collected by the Contractor

Table A2 presents the quality criteria the Contractor will use to evaluate the quality of data and information that the Contractor collects.

Table A-2. Criteria for the Evaluation of the Quality of Data Collected by the Contractor

Quality Criterion	Description/Definition		
Currency (up to date)	The information reflects present conditions.		
Geographic Scope	The information reported reflects an area relevant to the assessment.		
Reliability	 The information reported is reliable. For example, this criterion may include the following acceptance specifications: The information or data are from a peer-reviewed, government, or industry-specific source. The source is published. The author is engaged in a relevant field such that competent knowledge is expected (i.e., the author writes for an industry trade association publication versus a general newspaper). The information was presented in a technical conference where it is subject to review by other industry experts. 		
Unbiased	The information is not biased towards a particular product or outcome.		
Comparability	The data are comparable to other sources of acceptable quality.		
Representativeness	The data reflect the typical industry practices. The data are based on a large industry survey or study, as opposed to a case study or sample from a limited number of sites.		
Applicability	For surrogate data, the data are expected to be similar to the industry, property, or material of interest. The basis for determining applicability can vary case by case; for example, assuming applicability based on molecular similarity between two chemicals or process similarities between two industries.		

Data acceptance specifications will be established as follows:

- 1. EPA will provide to the Contractor the data acceptance specifications in written technical direction before the Contractor commences data collection.
- 2. Alternatively, EPA may task the Contractor to develop data acceptance specifications. EPA may direct the Contractor to begin preliminary data collection in order to develop data acceptance specifications. For example, EPA may task the Contractor to collect regulatory information to determine a data acceptance specification for the currency data quality criterion.
- 3. the Contractor will not develop data acceptance specifications if EPA neither provides them nor tasks the Contractor with their development. In this case, the Contractor will only document the quality of the collected data as described in Section 2.4.

1.3.2 Criteria for Evaluation of the Quality of Assessments or Other Technical Reports Prepared by Organizations Other than the Contractor

The Contractor will evaluate the quality of assessments and technical documents prepared by others, such as reports submitted to EPA by industry in the case of the PFOA Stewardship Program or the D4 Siloxane Environmental Monitoring Study Project, using the quality criteria presented in Table A-3.

Table A-3. Criteria for Evaluating the Quality of Assessments and Technical Reports Prepared by Other Organizations

Quality Criterion: Assessments and Technical	Description or Example
Reports	The industry is sufficiently described to provide a few detical few the
Adequacy	The industry is sufficiently described to provide a foundation for the overall assessment. The data sources are well documented and accessible.
Accuracy	There are no apparent mathematical errors or errors in logic.
Reasonableness	The assessment uses data or techniques that are from reliable sources or are generally accepted by the scientific community. The technical approaches are considered to be sound scientific knowledge.
Transparency	Assumptions, extrapolations, measurements, and models have been documented.
Clarity	The report is well organized and easily understandable by the target audience.
Completeness	All relevant exposure points and release sources have been addressed. Data gaps and conclusions have been identified and discussed.
Consistency	The technical approaches used to perform the assessment are comparable to approaches used in similar documents.

2. Data Acquisition, Review, Quality Verification, and Reporting

This section describes:

- How the Contractor will acquire data from the identified data sources; and
- How the Contractor will evaluate the collected data against the data quality criteria (see Section 2.3) and how the Contractor will document this evaluation.

2.1 Data Acquisition and Documentation

This section describes how the Contractor will acquire and document data sources and review data sources to acquire data needed to achieve project objectives.

2.1.1 Acquisition and Documentation of Data Collected via a Literature Search

To acquire data, the Contractor conducts a literature search using search keywords (see Section 1.2.1.1) and search engines (see Sections 1.2.1.2 and 1.2.1.3) to identify preliminary data sources that contain the data that are needed to achieve project objectives (see Section 4.1). The identification of data sources is accomplished by comparing information and data resulting from the search to the data needs of the project (see Section 1.1). The procedure for data acquisition is as follows:

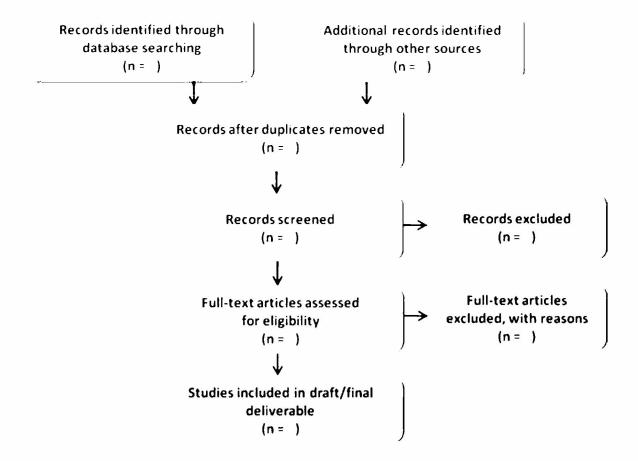
- Initial Filtering of Search Results: After all search keywords are applied, the Contractor selects
 the most relevant data sources from the search results for further consideration by reviewing
 the titles of the search results. the Contractor documents full citations for the selected data
 sources.
- 2. Secondary Filtering of Search Results: The Contractor selects data sources for further consideration by reviewing the abstracts or executive summaries of all of the data sources identified via the initial filtering. If abstracts or executive summaries are not available, the Contractor will acquire a data source and review the introduction and conclusion sections. The literature search can be tracked using a modified PRISMA flow diagram (Moher et al., 2009) shown in Figure A-1. The PRISMA flow diagram graphically illustrates the number of citations reviewed during the literature search process. This procedure allows to properly document the literature search process and results.
- 3. Data Source Acquisition and Storage: The Contractor acquires and stores all data sources selected as a result of the secondary filtering of search results as follows:
 - a. Download electronic publications and reports, usually as portable document format (PDF) files.
 - b. Download electronic databases, usually as spreadsheets or databases files; for example, the public version of EPA's CDR database.
 - c. Save web pages as PDF files, so that the data source can be added to the electronic project folder.
 - d. Record full bibliographic information (the citation) for all collected data sources in a tracking list specific to that project. Include the date accessed for webpages.
- 4. Review of Data Sources and Acquisition of Data: After acquiring and storing the data sources selected as a result of secondary filtering, the Contractor will review these data sources and determine if they contain data that are needed to achieve project objectives. The Contractor

typically transcribes data acquired from data sources to spreadsheets, databases, or text files (e.g., MS Word documents). The following is an example of such compilation ofdata:

Table A-4

Data Saurea	Engineering Data Need	Engineering Date or Information Found
e.g. 2012 non-CBI CDR	e.g., type # from Table A-1	e.g., process description, monitoring data, emission factor, etc.
Data	list	

Figure A-1.



2.1.2 Acquisition and Documentation of Primary Data

The Contractor may collect primary data from subject-matter experts by telephone and/or email. The Contractor staff will use the following procedures when collecting data via telephone and email contact:

- the Contractor researchers will document all telephone contacts using the Telephone Contact Report depicted in Figure 5-1 and save them to the electronic project folder.
- the Contractor researchers will save all email exchanges as PDF files and add themto the electronic project folder.

2.2 Data Storage and Management

As determined necessary by the Contractor WAM, the Contractor will create a new electronic project folder for each project on the Contractor's local network.

The Contractor will store electronic copies of all collected data sources in the electronic project folder, including data sources that contain data evaluated against the quality criteria and found to be not acceptable and, hence, were not used in the project. the Contractor will also save electronic copies of websites to the electronic project folder in PDF, since web links frequently change. Hard copies of sources not electronically available will also be documented and placed in a centralized project file.

The Contractor will maintain a tracking list of all collected data sources. If directed to do so by EPA in technical direction, the Contractor will use EndNote to document the data sources used in the project (using the most recent version of EndNote in the Contractor's possession). the Contractor will deliver the EndNote Library file to the EPA Task Manager and EPA WA COR when delivering final deliverables.

2.2.1 Obtaining CBI Data from EPA

EPA will transfer TSCA CBI to the Contractor on electronic media (e.g., CD-ROM, ZIP-disk) or as a hardcopy to the Contractor's TSCA CBI-approved Secure Storage Area (SSA) in Chantilly, VA (last inspected and approved for use and storage of TSCA CBI on April 12, 2004). The following procedures will be used to transfer documents, as discussed in the TSCA CBI Security Manual (EPA, 2003b):

- The EPA TSCA CBI Document Control Officer (DCO) will appropriately package the hardcopy documents or the electronic media (e.g., CD-ROM, ZIP-disk) containing the documents.
- The EPA TSCA CBI DCO will fill out a TSCA CBI transfer receipt and complete the appropriate EPA CBI transfer log.
- The package containing the documents will be hand-carried by a TSCA CBI-cleared individual from EPA directly to the Contractor TSCA CBI DCO or will be appropriately packaged and mailed per the TSCA CBI Security Manual (EPA, 2003b) by the EPA TSCA CBI DCO to the Contractor TSCA CBI DCO.
- The Contractor TSCA CBI DCO will sign, copy, and return the TSCA CBI transfer receipt, enter the documents in the Contractor's TSCA CBI Document Tracking System (DTS),

and place the documents in the Contractor's TSCA CBI-approved SSA.

2.2.2 Procedures for Analyzing CBI Data

Analysis of CBI data will be conducted by the Contractor TSCA CBI-cleared personnel in a TSCA CBI-approved SSA. the Contractor analysis results may be intended for internal EPA use or for the general public. In either case, CBI contained in the Contractor products may need to be masked. The need for CBI masking will be determined, in consultation with the EPA WA COR or Task Manager, prior to beginning work with TSCA CBI.

To ensure the protection of CBI in all work products developed by the Contractor, the Contractor WAM or designee will review all work products to determine if any CBI is included in the work products. If any CBI is identified or if there is any uncertainty whether the information is CBI, the Contractor will transmit the work product to EPA following the CBI handling and transmission procedures, similar to those presented in Section 2.2.1.

2.3 Data Review

According to EPA's Guidance for QAPPs (QA/G-5) (EPA, 2002b), data review is "the in-house examination to ensure that the data have been recorded, transmitted, and processed correctly. That includes, for example, checking for data entry, transcription, calculation, and reduction errors...It is a completeness check to determine if there are any deficiencies, such as data missing...."

If the Contractor downloads or copies data from an existing database or spreadsheet, we will review the downloaded data to ensure the data were downloaded correctly. The review of data obtained from an existing database would typically require checks for any data errors, such as missing data and registry errors.

2.4 Data Quality Verification

According to EPA's Guidance for QAPPs (QA/G-5), data verification is "the process of evaluating the completeness, correctness, and conformance of a specific data set against the method, procedural or contractual specifications." For this Task Order, data verification means the process in which the Contractor will evaluate collected data against the project data acceptance specifications discussed in Section 1.3.

To evaluate, or prepare for an evaluation by EPA, of whether collected data are fit for purpose (see Section 1.3), the Contractor collects metadata for all collected data. Metadata are data or information that describe the collected data and include, but are not limited to, the following:

- Number of samples collected by study authors in a monitoring study;
- Number of sites or workers included in a survey;
- Full bibliographic information of the data source;
- Date of the data source; and
- Date of the data within the data source (for example, an article published in 2015 may

cite data from 2000).

The Contractor compiles metadata that are relevant to the quality criteria listed in Table A-2 in a Data Source Review Summary Sheet, which is in text file format (i.e., in a MS Word document) or in spreadsheet or database format. Data Source Review Summary Sheets will be retained in the electronic project folder to document the Contractor's evaluation of the quality of the collected data. An example of such table is given below. If data acceptance specifications are established for the project, the Contractor will determine whether or not the collected data are fit for purpose by comparing the compiled metadata with the acceptance specifications. The Contractor will document the results of the evaluation on the Data Source Review Summary Sheet. The Contractor may use data that do not meet the acceptance specifications if, for example, there are no other available data. The Contractor will obtain the written approval of the EPA Task Manager before using such data. This approval will be added to the electronic project folder. The Contractor will discuss the use of data that did not meet acceptance specifications in the relevant project deliverable.

If EPA neither provides acceptance specifications nor tasks the Contractor with their development, the Contractor will only compile the metadata in a Data Source Review Summary Sheet and the EPA Task Manager will determine whether the data are acceptable for use.

Table A-5: Data Source Summary Sheet

Data Sources	Year(s) of Data	Geographical Scope	Reliability	Unbiased	Comparability, Representativeness, and Applicability	Key Information Found
e.g. 2012 non-CBI CDR Data			e.g. Government resource	e.g. Unbiased	e.g. CDR data are representative of US production and import of chemicals in large quantities	e.g., process description, monitoring data, emission factor, etc.

2.5 Data Quality Reporting

This section describes the data quality reports the Contractor will prepare and submit to EPA.

2.5.1 Report on the Acquisition and Review of Data Sources and Data Quality Verification

The Contractor will report the following to the EPA Task Manager and EPA WA COR as soon as data quality verification is completed:

- 1. The number of and full citations for the data sources that resulted from the initial filtering of literature search result (see Section 2.1.1).
- The number of and full citations for the data sources that were discarded and not considered
 any further after secondary filtering and after reviewing data sources in full (see Section 2.1.1),
 and the rationale for discarding the data sources.
- 3. The number of and full citations for the data sources for which the Contractor performs data quality verification, and the Data Source Review Summary Sheet (see Section 2.4), which will include documentation of data quality and a determination of whether the data contained in each data source are fit for purpose if data acceptance specifications were provided by EPA or developed by the Contractor for the project.

2.5.2 Report on Systematic Review

At EPA's request, the Contractor will integrate the approved Plan for Collection of Fit-For-Purpose Data and the Report on the Acquisition and Review of Data Sources and Data Quality Verification into a single summary report that may be included in Work Plan Chemical scoping and/or risk evaluation reports.

3. Use of Existing Data

The Contractor will use existing data to:

- Provide a summary of the reviews and analyses of data that are requested by EPA; and
- Develop a chemical assessment.

3.1 Using Existing Data: Review, Analysis, and Summary or Development of Chemical Assessments

The Contractor may collect existing data for review, analysis, and summary, or for the development of a chemical assessment. The specific data analyses that will be required are not known at this time; however, similar analyses typically involve the development of spreadsheets, databases, and database queries. The Contractor anticipates performing the following types of analyses:

- Engineering calculations;
- Statistical calculations; and
- Calculations using mathematical models.

3.2 Technical Review of Data Analysis

The Contractor will implement a conceptual review, a developmental review, and a final product technical review for the review, analysis, and summary of existing data, and developing chemical assessments. The Contractor team members will revise approaches, methodologies, calculations, analyses, written works, and all deliverables based on the results of each of these three technical reviews. Conceptual review, developmental review, and final product technical review are discussed in Sections 3.2.1, 3.2.2, and 3.2.3, respectively.

3.2.1 Conceptual Review

The Contractor will plan an approach or develop a methodology. The Contractor WAM or designee will review the approaches or methodologies; that is, he or she will provide conceptual review. His or her review will ensure the alignment of the Contractor's work with project objectives early in the work

process. The Contractor tailors the level of review to the project complexity, budget, and schedule. Highly technical approaches or methodologies may require a conceptual review by a technical reviewer with expertise in the subject matter. As an example, a methodology for the development of a mathematical exposure model would require the conceptual review by a Contractor modeling expert. The Contractor Task Leader will discuss the approaches and methodologies developed by the Contractor with the EPA Task Manager.

3.2.2 Developmental Review

As described in Section 3.1, the use of existing data is expected to involve calculations or analyses that typically require the development of spreadsheets, databases, and database queries.

To ensure the quality of the spreadsheets developed, the Contractor WAM ensures resources are available for their review. The review of a spreadsheet will follow the Contractor's standard procedures, which include the following general steps:

- The spreadsheet developer verifies the accuracy of any data that were transcribed into the spreadsheet;
- A team member reviewer, such as a team member knowledgeable of the project but
 who did not develop the spreadsheet, reviews the spreadsheet to ensure the accuracy
 of the calculations as they were intended by the spreadsheet developer (i.e., are the
 calculations performed accurately according to the equation(s) prescribed by the
 spreadsheet developer);
- The team member reviewer also verifies the accuracy of any data that were transcribed into the spreadsheet;
- The team member reviewer evaluates the technical soundness of methods and approaches used;
- The Contractor Task Leader is responsible for version control, of interim spreadsheets;
 and

• The Contractor Task Leader is responsible for maintaining documentation in the project files.

The Contractor will develop databases using the Contractor standard procedures, which include the following general steps:

- Any data entry required during the development of the database will be verified by a
 project team member other than the one who performed the data entry.
- Where possible, the Contractor will import tables from the source (such as from *.txt,
 *.csv, *.xls, and *.xlsx files) directly into the database to eliminate key entry errors.
- the Contractor will review the imported tables to ensure the import occurred correctly, such as by verifying that the correct number of records was imported into the database.

The Contractor will check the accuracy of database queries that are used to compile and aggregate data by following the Contractor standard procedures, which include the following general steps:

- The query developer creates documentation that describes each query's purpose and design methodology, documents all constants and unit conversions, and provides sufficient documentation for the team member reviewer to reproduce the results.
- The team member reviewer verifies that the query developer provided a reasonable and appropriate approach, accurate calculations and queries, and complete and clear documentation, and that the query functions as designed.

The Contractor will maintain documentation of the reviews described above in the electronic project folder, in the form of mark-ups, track changes, and comments in working files.

3.2.3 Final Product Technical Review

Before delivery to EPA, all project deliverables will be reviewed by the Contractor WAM or designee. This review will be documented using document review sign-off sheets. This documentation will be retained at the Contractor in the electronic project folder. Section 4 summarizes the different levels of review for various work product types anticipated under this Task Order.

All project deliverables will meet EPA's standards of transparency, objectivity, integrity, and utility as specified in EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (EPA, 2002a). In this context, "transparency" means that documentation supporting the work presented in deliverables identifies the sources of data and assumptions made to ensure the reproducibility of the work by qualified third parties. Additionally, the Contractor will review written deliverables (such as reports and memoranda) to ensure the use of clear technical writing during WAM and technical reviewer reviews. Any issues that arise during the preparation of the deliverables will be presented to the EPA WA COR and Task Manager for resolution.

Table A-6 summarizes the quality criteria the Contractor will use to guide the Contractor's review of the Contractor's chemical assessment reports.

Table A-6. Quality Criteria for the Contractor's Chemical Assessment Reports

Quality Criterion:	
Assessment Report	Description/Definition
Adequacy	The industry is thoroughly described to provide a foundation for the overall assessment. The data sources are well documented and accessible.
Reasonableness	The assessment uses data or techniques that are from reliable sources or are generally accepted by the scientific community. The technical approaches are considered to be sound scientific knowledge.
Transparency	Assumptions, extrapolations, measurements, and models have been documented.
Clarity	The report is well organized and easily understandable by the target audience.
Completeness	The assessment achieves the objectives of the task. Data gaps and conclusions have been identified and discussed.

3.3 Validation of Analysis Results

According to EPA's Guidance for QAPPs (QA/G-5), data validation is "an analyte- and sample-specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set."

The Contractor will support EPA in validating the results of calculations conducted during the development of exposure and release assessments by using engineering judgment to evaluate whether the estimates "make sense" in the context of our knowledge of the given industry and based on past experiences conducting chemical assessments. This evaluation may include analysis of the results, for example comparison of calculated indoor air concentrations with applicable OSHA PELs.

3.4 Reconciliation with User Requirements

The Contractor will identify the sources of data, assumptions made, and calculations used in their development in all project deliverables. These identifications will be sufficiently detailed and transparent to ensure the reproducibility of the work by qualified third parties.

The Contractor will include an evaluation of data and data analysis quality in all project final reports.

The Contractor's final reports will include a discussion of the limitations on the use of the data. The project final reports will provide an assessment of how well the data collected and analyzed meet project objectives identified in the project technical direction.

4. Project Reports (Deliverables)

The deliverables EPA will require under this Task Order are not known at this time and are likely to vary for each project. In general, deliverables under Tasks 2 and 3 of this Task Order are expected to include:

- Spreadsheets and calculations;
- Databases and database queries;
- Memoranda;
- Reports; and
- Briefing and presentation materials.

Deliverables under this Task Order will be reviewed as described in Section 3.2.3. Table A-7 provides the levels of review that the Contractor will typically employ for each type of deliverable expected under this Task Order. The exact levels of review for a given work product type may vary depending upon EPA's schedule and budget. the Contractor will discuss the appropriate levels of review for a work product with the EPA Task Manager prior to review if the planned levels of review differ from those indicated in Table A-7. The Contractor will inform the EPA Task Manager of the levels of review actually performed when delivering the work product. The Contractor will inform the EPA Task Manager if the

Contractor did not complete a full review of major deliverables at the time of delivery of the deliverable. This notification is intended to assure that EPA is aware that such deliverables may not be final.

Table A-7. Required Levels of Review for Types of Work Products Anticipated Under this Task Order

Work Product Type	Team Member ^a	Technical Reviewer ^b	the Contractor WAM ^c	Technical Editor ^d
Internal project memoranda (for communication between the Contractor and EPA)	х		х	
Spreadsheets/calculations	х	х		
Database and database queries	Х	х		
Briefing and presentation materials			Х	
Reports and project deliverables ^e	Х		Х	Х

a – Review by a team member familiar with the work who did not perform the task, often the Task Leader.

b – Technical Review is conducted by a qualified staff member who is not directly involved in the project.

- c The WAM may designate an alternate reviewer in place of the WAM review, as appropriate.
- d Technical edits will only be performed at the request of the EPA WA COR or Task Manager.
- e The EPA Task Manager may request additional levels of review depending on the purpose and audience of the report as appropriate. Note that the Contractor Technical Reviewer will review spreadsheets/calculations and databases and database queries described in the report.

Source		Search Procedures		
U.S. EPA	CDR	Go to ChemView: http://java.epa.gov/chemview Use the search field to search by CAS number or chemical name and specify data filter criteria.		
	HPV Challenge Submissions	Go to the following website: http://cfpub.epad.gov/hpv%2Ds/ Search for voluntary high production volume (HPV) chemical submissions using CAS number, chemical or chemical category name.		
		HPV chemicals that are produced or imported in the U.S. in quantities of 1 million pounds or more. HPV submissions typically contain information on general uses, manufacturing process, and potential routes of release and exposure.		
	EHPV Program Submissions	Go to the following website: http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail-8d=EPA-HQ-OPPT-2006-1020 Search for voluntary extended high production volume (EHPV) chemical submissions using a keyword search in the EPA docket.		
	EPA Existing Chemicals Engineering Files	EPA has an archive of hardcopy engineering assessments from previous Existing Chemicals assessments. If directed by the EPA Task Manager, ERG will contact the EPA WA COR to inquire as to the location of these hardcopy files and will review them for relevant information.		
	EPA Generic Scenarios	Review the list of currently approved Generic Scenarios for relevant information. The scenarios provide information on process descriptions and guidelines for release and exposure estimates for specific industry sectors.		
	TRI	Go to the following website: http://www2.epa.gov/toxics-release-inventory-tri-program Review the list of Industry Specific Guidance Documents for information relevant to industries of interests.		
		If you are interested in facility-specific TRI data (e.g., every facility that formulates auto refinish coatings may report to TRI; therefore, you may be able to use TRI data to estimate the number of facilities), you can use TRI Explorer located at http://www.epa.gov/triexplorer/ . Additionally, TRI raw data files are also available through the EPA TRI website (http://www2.epa.gov/toxics-release-inventory-tri-program).		
	NEI	Go to the following website: https://www.epa.gov/air-emissions-inventories/national-emissions-inventory Review relevant emission data for the most recent reporting year and download publicly available databases.		

Office of Water	Go to the following website: http://www.epa.gov/OST/guide/
	Review the list of final, proposed, and other guidelines under development for
	information relevant to the industry.

Source		Search Procedures		
	Office of Air	Go to the following website: http://www.epa.gov/ttn/atw/eparules.html Review the list of NESHAP regulations and supporting documentation for information relevant to the industry. Go to the following website: http://www.epa.gov/ttn/chief/eiip/techreport/ Review the EIIP, specifically Volume 2, for guidance documents relevant to the industry.		
	OECA Sector Notebooks	Go to the following website: http://www.epa.gov/compliance/resources/publications/assistance/sectors/n otebooks/index.html http://www.epa.gov/compliance/resources/publications/assistance/sectors/n http://www.epa.gov/compliance/resources/pu		
	AP-42	Go to the following website: http://www.epa.gov/ttn/chief/ap42/index.html Read through the different chapters for information relevant to the industry. Note that some of the chapters are fairly broad and may contain information that may not be completely intuitive from just reading the chapter title. For example, Chapter 6: Organic Chemical Process Industry contains information on Printing Inks, Soaps and Detergents, as well as chemical specific information.		
	Other EPA (e.g., DfE)	Go to the following website: http://www.epa.gov/ Enter each keyword or phrase in the search tool. Review the results for relevant information not identified through other EPA searches.		
OSHA		Go to the following website: http://www.osha.gov/ Enter each keyword or phrase in the search tool. Review the results for relevant information. Determine whether OSHA Permissible Exposure Limit (PEL) has been established for specific chemicals of interest.		
NIOSH		Go to the following website: http://www.cdc.gov/NIOSH/ Enter each keyword or phrase in the search tool. Review the results for relevant information. Determine whether NIOSH recommended Exposure Limit (REL) has been established for specific chemicals of interest. Note that this search tool will also search all HHE's.		
ACGIH		Search the ACGIH handbook to determine whether ACGIH Threshold Limit Value (TLV) has been established for specific chemicals of interest. A copy of the handbook is available at the ERG library.		
ATSDR		Go to the following website: http://www.atsdr.cdc.gov/toxprofiles/index.asp Enter a chemical name or CAS number in the search tool. Review the results for relevant information and to determine whether a toxicological profile is available.		

Source		Search Procedures		
SRI		Since SRI data are proprietary and can only be made publicly available with permission from SRI, ERG will only search for and collect SRI data at the direction of the EPA Task Manager. The steps for searching for and collecting SRI data are: Contact EPAB's library coordinator (currently Bill Silagi) and set up a time to go to the library at EPA. He will have a confidentiality form you must sign. Review the table of contents and indexes of the SRI volumes for the keywords. Photocopy or take notes on any pages of interest. Note that each page must clearly state at the top that it contains proprietary information. The EPA WA COR must request permission if the information will be made publicly available.		
OECD	General Site	Go to the following website: http://www.oecd.org Enter each keyword or phrase in the search tool. Review the results for relevant information.		
	SIDS	Search for screening information data set (SIDS) documents using chemical name and/or CAS number at the following websites: http://www.oecd.org and http://www.oecd.org and http://www.oecd.org and http://www.oecd.org and		
	ESDs	Review the list of published ESDs located at http://www.oecd.org/document/46/0,2340,en 2649 201185 2412462 1 1 1,00.html Review the list of draft ESDs and projects in preparation also available on the above website. If any of the ESDs appear to be potentially applicable, contact Greg Macek (macek.greg@epa.gov) and Nhan Nguyen (nguyen.nhan@epa.gov) to determine the status of these ESDs and obtain available documents.		
Environment Canada	General Site	Go to the following website: http://www.ec.gc.ca/default.asp?lang=En&n=FD9B0E51-1 Enter each keyword or phrase in the search tool. Review the results for relevant information.		
	Canadian P2 Information Clearinghouse	Go to the following website: http://www.ec.gc.ca/cppic/en/index.cfm Enter each keyword or phrase in the search tool. Review the results for relevant information.		
U.S. Census Bureau	NAICS Determination	Go to the following website: http://www.census.gov/eos/www/naics/ Enter each keyword or phrase in the search tool. Review the results to determine the applicable NAICS code(s) for the industry. A bridge between SIC and NAICS codes is also located at http://www.census.gov/eos/www/naics/concordances/concordances.html .		
	County Business Patterns	Go to the following website: http://www.census.gov/econ/cbp/index.html Locate the CBP data for the applicable NAICS code(s).		
	Annual Survey of Manufacturers	Go to the following website: http://www.census.gov/manufacturing/asm/index.html Locate the ASM data for the applicable NAICS code(s), if available.		

Source		Search Procedures		
	Current Industrial Reports	Go to the following website: http://www.census.gov/manufacturing/cir/index.html Review the list of CIRs for data applicable to the industry.		
	Economic Census	Go to the following website: http://www.census.gov/econ/census/data/ Locate the Economic Census data for the applicable NAICS code(s) using the Industry Statistics Portal (ISP).		
Bureau of Labor Statistics (BLS)		Go to the following website: http://www.bls.gov/ Review available publications for relevant information (e.g. industry statistics on the number of workers).		
NC Division of P Prevention and Assistance	AUGUST AUGUST	Go to the following website: http://www.p2pays.org/ Enter each keyword or phrase in the search tool. Review the results for relevant information.		
Kirk-Othmer Encyclopedia of Chemical Technology		Go to the following website: http://onlinelibrary.wiley.com/mrw/advanced/search?doi=10.1002/04712389 61 Enter each keyword or phrase in the search tool. Review the results for applicable entries in the encyclopedia. Note: ERG currently has access to the latest edition through an online subscription.		
Hazardous Substances Data Bank (HSDB)		Go to the following website: http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB Enter CAS number or chemical name in search tool. Review results for relevant information.		
National Library of Medicine's HazMap		Go to the following website: http://hazmap.nlm.nih.gov/index.html Enter chemical name and/or CAS number in the search tool. Review results for available information. HazMap provides information on health effects associated with exposure to certain chemicals and biological agents found in workplaces, and specifies the chemical's sources, uses, and industrial processes with risk of exposure.		

ATTACHMENT 2: QUALITY ASSURANCE SURVEILLANCE PLAN

PERFORMANCE REQUIREMENT	PERFORMANCE MEASURE (PM)	PERFORMANCE STANDARD	SURVEILLANCE METHOD	INCENTIVES & DISINCENTIVES
MANAGEMENT AND COMMUNICATION: The contractor shall maintain contact with the EPA CO, COR, and TOCOR throughout the performance of the contract.	Contractor shall immediately bring potential problems to the appropriate EPA personnel and shall recommend actions that would mitigate or resolve the problem.	Issues that impact project schedules and costs shall be brought to the attention of the EPA within 3-days of occurrence.	All active task orders will be reviewed by the EPA to identify unreported issues.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Business Relations in the Contractor Performance Assessment Reporting System (CPARS).
TIMELINESS: For every Task Order awarded establishing a firm, specific delivery date for the generation of a report, the contractor shall deliver such report to the COR, TOCOR and CO no later than the time specified in the order's PWS.	Deliverables and related work must comply with contractual timeliness requirements. The contractor will be evaluated on its responsiveness to all task orders.	95% of all deliverables and related work shall be completed on time within task schedule and/or tech. direction requirements.	100% inspection of all deliverables and related work by the TO COR; TO COR will document the timeliness of all work requirements.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Timeliness in the Contractor Performance Assessment Reporting System (CPARS).
TECHNICAL QUALITY: For every task order awarded, the analyses conducted by the contractor shall be factual, defensible, credible, and based on sound scientific methods. All data shall be collected from reputable sources and quality assurance measures shall be conducted in accordance with the agency requirements outlined in the task orders.	All deliverables and related work must be complete, accurate, thorough, and professionally credible.	Data are 100% accurate; review demonstrates a high level of expertise and credibility with regards to personnel and use of scientific methodology. Task Orders shall be conducted in strict conformance with approved QA plans. Outputs shall withstand internal review by the US EPA and outside scientific reviewers.	EPA Staff will conduct secondary reviews of work completed by the contractor. Feedback will be provided.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation in the category of Quality of Product or Service in the Contractor Performance Assessment Reporting System (CPARS).